

***Remarks***

***I. Support for Amendments***

The forgoing amendments do not add new matter, and their entry and consideration are respectfully requested. These amendments are sought to place the claims into condition for allowance or into better form for consideration on appeal. The amendments to claims 1 and 41 are sought to accommodate the Examiner's suggested amendments to claims 34-37 and 41, and are believed to bring these claims into condition for allowance as acknowledged by the Examiner in Paper No. 27 at page 7. The amendments to claims 1 and 41 represent the incorporation of dependent claim 34 into independent claim 1, and the incorporation of independent claim 33 into previously dependent claim 41. Moreover, the amendment to independent claim 37 is sought to exclude certain subject matter from the scope of this claim, and to place this claim into the same general form as independent claims 1 and 41. Applicants note that claims 1, 33, 34, 37 and 41 have all been searched and examined in the present application, and no additional matter has been added to claims 1, 37 and 41. Hence, Applicants respectfully submit that no new or additional search need be conducted on current claims 1, 37 and 41, and entry and consideration of the after final amendments to these claims is proper.

In any event, support for the foregoing amendments to the claims can be found in the specification as originally filed. Specifically, support for the amendments to claims 1, 37 and 41 can be found in the specification at pages 7-11, throughout the Examples, in the drawings

at Figures 2-4, and in the claims as originally filed. Accordingly, no new matter is added by these amendments, and their entry and consideration are respectfully requested.

## ***II. Status of the Claims***

By the foregoing amendments, claims 33-36, 38 and 39 have been cancelled without prejudice to or disclaimer of the subject matter encompassed thereby; Applicants reserve the right to prosecute the subject matter of these cancelled claims in one or more continuing applications. Also by the foregoing amendments, claims 1, 37 and 41 are sought to be amended. Upon entry of these amendments, claims 1-9, 11-28 and 33-41 are pending in the application, with claims 1, 37 and 41 being the independent claims and with claims 11-16 having been withdrawn from consideration by the Examiner.

## ***III. Summary of the Office Action***

In the Office Action dated June 18, 2003, the Examiner has objected to claims 34-37 and 41 for being dependent from a rejected base claim, but has noted that these claims would be allowable if rewritten in independent form. Applicants thank the Examiner for noting the potential allowability of these claims, which is addressed in detail below.

In addition, the Examiner has maintained the withdrawal of claims 11-16 from consideration, and has made six rejections of the claims. Applicants respectfully offer the following remarks to overcome or traverse each element of this rejection in the Office Action.

**IV. Objection to Claims 34-37 and 41, and Allowable Subject Matter**

Applicants first note that the Examiner has objected to claims 34-37 and 41 as being dependent upon a rejected base claim. *See* Office Action at page 7. The Examiner has also stated that claims 34-37 and 41 would be allowable "if rewritten in independent form including all of the limitations of the base claim and any intervening claims." *Id.* By the foregoing amendments, claim 41 has been rewritten in independent form, incorporating the limitations of claim 33 from which claim 41 had depended, as requested by the Examiner. Accordingly, as the Examiner has acknowledged, claim 41 as amended is allowable; reconsideration and withdrawal of the objection, and allowance of claim 41, therefore are respectfully requested.

In addition, by the foregoing amendments the limitations of claim 34 (*i.e.*, a uricase that "contains no more than about 2% of aggregates larger than octamers") have been incorporated into claim 1, from which claim 34 had depended. Applicants contend that the amendment to claim 1 places this claim into the same form as claim 34 would be if it were "written in independent form including all of the limitations of the base claim [*i.e.*, claim 1]" as requested by the Examiner. That is, instead of rewriting claim 34 in independent form by incorporating the limitations of claim 1 into it, Applicants have rewritten independent claim 1 by incorporating the limitations of dependent claim 34 into *it*. The Examiner has acknowledged that claim 34 would be allowable if it were rewritten in independent form incorporating the limitations of claim 1. Therefore it follows that the converse, in which claim 1 is rewritten to incorporate the limitations of claim 34, is also allowable since claim

1 as currently presented is substantially the same as claim 34 would be if it were rewritten as requested by the Examiner. Accordingly, reconsideration and withdrawal of this objection, and allowance of claim 1 (and the claims that depend therefrom), are respectfully requested.

Claims 35 and 36, which were also objected to, have been cancelled. However, Applicants note that claims 35 and 36 recited a uricase that "contains no more than about 2% of aggregates larger than octamers." As noted above, this limitation has been incorporated into claim 1, and is believed to place this claim into allowable form. Claim 35 depended from claim 17, which in turn depends from claim 1. Similarly, claim 36 depended from claim 27, which in turn depends from claim 17 and hence ultimately from claim 1. Thus, by rewriting claim 1 to recite a uricase that "contains no more than about 2% of aggregates larger than octamers," claims 17 and 27, through their dependence upon claim 1, contain the same limitation. Accordingly, reconsideration and withdrawal of this objection, and allowance of claim 17 and 27 (and the claims that depend therefrom), are respectfully requested.

Finally, Applicants respectfully submit that the objection to claim 37 is in error. In objecting to claim 37, the Examiner contends that this claim "would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." Paper No. 27 at page 7. Applicants note, however, that claim 37 already *is* an independent claim; unlike claims 34-36, claim 37 does not depend directly or ultimately from claim 1. Hence, there is no "base claim" and there are no "intervening claims" from which limitations could or should be obtained for inclusion into claim 37. For reasons detailed below, claim 37 is not anticipated or rendered obvious by the cited art. Moreover, the

Examiner has acknowledged the allowability of claim 37 at page 7 of the present Office Action. Accordingly, it is respectfully believed that the objection to claim 37 is in error; reconsideration and withdrawal of the objection, and allowance of claim 37, therefore are respectfully requested.

In view of the foregoing remarks, Applicants respectfully assert that independent claims 1, 37 and 41 are allowable, as acknowledged by the Examiner in the present Office Action. Applicants further respectfully assert that claims 2-9, 11-28 and 40, which depend directly or ultimately from claim 1, therefore are also allowable. Hence, reconsideration and withdrawal of all outstanding objections and rejections, and allowance of all pending claims, are respectfully requested.

Applicants believe that the foregoing remarks are sufficient to overcome all outstanding objections and rejections, particularly in view of the Examiner's acknowledgment of the allowability of the claims in their present form. Accordingly, it is respectfully believed that allowance of all pending claims is proper, and early notification to this effect is earnestly solicited. However, in order to comply fully with the requirements of 37 C.F.R. § 1.111(b), Applicants also offer the following remarks concerning the remaining portions of the Office Action.

**V. Election/Restrictions**

Applicants note that the Examiner has again indicated on the Office Action Summary (Form PTO-326) attached to Paper No. 27 that claims 11-16 are withdrawn from consideration.<sup>1</sup> This statement is also made in the Office Action at page 2, wherein the Examiner again contends that claims 11-16 are "drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6." Paper No. 27 at page 2, lines 6-8 (emphasis in original). Applicants respectfully disagree with these contentions.

Applicants respectfully assert that generic claim 1 and dependent claim 2 (encompassing the elected species, mammalian uricase) are allowable, in view of the remarks contained above and elsewhere herein. Claims 11-16 are all drawn to specific non-mammalian uricases, and depend directly or ultimately from generic claim 1. Thus, claim 1 represents an allowable generic claim that links claims 11-16 and the elected species recited in claim 2. Accordingly, it is respectfully requested that claims 11-16 be rejoined and examined with the remaining claims in restriction group I, and that these claims be allowed. *See* 37 C.F.R. § 1.141(a) and 1.146, and MPEP § 809.02(c)(B).

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<sup>1</sup>Applicants note that despite the indication on Form PTO-326 that claims 11-16 are withdrawn from consideration, these claims are also listed thereon as being rejected. *See* Form PTO-326 attached to Paper No. 27, "Disposition of Claims," Item 6. As noted herein, it is respectfully believed that claims 11-16 should be rejoined and examined, and are allowable. Clarification of the status of claims 11-16 is respectfully requested.

***VI. The Rejection Under 35 U.S.C. § 102(e) Over Williams Is Traversed***

In the Office Action at pages 2-3, the Examiner has rejected claims 1-9, 17-28 and 33-41 under 35 U.S.C. § 102(e) as being anticipated by Williams *et al.*, U.S. Patent No. 6,576,235 (Doc. No. A1 on the Form PTO-892 attached to Paper No. 27; hereinafter "Williams"). Applicants respectfully traverse this rejection.

As an initial matter, Applicants note that the Examiner has indicated that claims 33-41 are rejected over Williams. However, as discussed above, the Examiner has also indicated that claims 34-37 and 41 would be allowable if rewritten in independent form. See Paper No. 27 at page 7. This indication of the allowability of these claims in independent form clearly evidences the Examiner's conclusion that claims 34-37 and 41 are not anticipated by Williams. Accordingly, it is respectfully believed that the inclusion of claims 34-37 and 41 in the present rejection was in error; reconsideration and withdrawal of this portion of the rejection are therefore respectfully requested.

In any event, for reasons unrelated to the present rejection, claims 33-36, 38 and 39 have been cancelled without prejudice or disclaimer. Thus, the portion of this rejection that may have applied to these claims has been rendered moot.

As noted above, claims 1 and 41 have been amended to place them into a form acknowledged by the Examiner to be allowable. Hence, claims 2-9, 17-28 and 40, which depend directly or ultimately from allowable claim 1, are in turn allowable. Accordingly,

reconsideration and withdrawal of the rejection of claims 1-9, 17-28, 40 and 41 over Williams are respectfully requested.

Finally, Applicants note that claim 37 has been rejected as allegedly being anticipated by Williams. Applicants respectfully traverse this rejection, and assert that Williams does not disclose all of the elements of claim 37 as currently presented. Accordingly, reconsideration and withdrawal of this portion of the rejection are respectfully requested.

In view of the foregoing remarks, Applicants respectfully assert that the invention as presently claimed is not anticipated by Williams. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e) over Williams therefore are respectfully requested.

#### ***VII. The Double-Patenting Rejection***

In the Office Action at pages 3-4, the Examiner has rejected claims 1-9, 17-28 and 33-41 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-33 of Williams. Applicants respectfully traverse this rejection.

As an initial matter, Applicants again note that the Examiner has rejected claims 33-41 over Williams. However, as discussed above, the Examiner has also indicated that claims 34-37 and 41 would be allowable if rewritten in independent form. *See* Paper No. 27 at page 7. This indication of the allowability of these claims in independent form clearly evidences the Examiner's conclusion that claims 34-37 and 41 are not unpatentable over claims 1-33 of Williams. Accordingly, it is respectfully believed that the inclusion of claims 34-37 and 41



in the present rejection was in error; reconsideration and withdrawal of this portion of the rejection are therefore respectfully requested.

In any event, for reasons unrelated to the present rejection, claims 33-36, 38 and 39 have been cancelled without prejudice or disclaimer. Thus, the portion of this rejection that may have applied to these claims has been rendered moot.

As noted above, claims 1 and 41 have been amended to place them into a form acknowledged by the Examiner to be allowable. Hence, claims 2-9, 17-28 and 40, which depend directly or ultimately from allowable claim 1, are in turn allowable. Accordingly, reconsideration and withdrawal of the double patenting rejection of claims 1-9, 17-28, 40 and 41 over claims 1-33 of Williams are respectfully requested.

Finally, Applicants note that claim 37 has been rejected as being unpatentable over claims 1-33 of Williams. Applicants respectfully traverse this rejection, and assert that claim 37 as currently presented would not have been obvious over claims 1-33 of Williams. Accordingly, reconsideration and withdrawal of this portion of the rejection are respectfully requested.

In view of the foregoing remarks, reconsideration and withdrawal of the double patenting rejection over claims 1-33 of Williams are respectfully requested. However, should the Examiner not be inclined to reconsider and withdraw this rejection, Applicants respectfully request that it be held in abeyance until the allowance of all pending claims in the present application, at which time Applicants will consider filing a terminal disclaimer.

**VIII. The Rejection Under 35 U.S.C. § 102(b) Over Aleman**

In the Office Action at pages 4-5, the Examiner has rejected claims 1, 4, 6 and 33 under 35 U.S.C. § 102(b) as being anticipated by Aleman *et al.*, U.S. Patent No. 5,811,096 (Doc. No. A1 on the Form PTO-892 attached to Paper No. 24; hereinafter "Aleman"). By the foregoing amendments, claim 33 has been cancelled without prejudice or disclaimer, thus rendering moot the portion of this rejection that may have applied to claim 33. Applicants respectfully traverse this rejection as it may be applied to claims 1, 4 and 6.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). This requirement is not met by the disclosure of Aleman.

Claim 1 as currently presented (and hence, claims 4 and 6 that depend directly or ultimately from claim 1) recites a purified uricase that contains no more than about 2% of aggregates larger than octamers. Applicants respectfully assert that Aleman does not expressly or inherently disclose uricases containing no more than about 2% of aggregates larger than octamers. Indeed, Aleman is silent on this issue, and the Examiner has pointed to no explicit statement in Aleman that the uricase disclosed therein contains no more than about 2% of aggregates larger than octamers. In fact, the Examiner has acknowledged that Aleman does not disclose such uricases by not including in this rejection previous claims 34-37, all of which recite uricases containing no more than about 2% of aggregates larger than octamers.

Accordingly, Aleman does not expressly or inherently disclose every element of the invention as claimed.

In view of the foregoing remarks, Applicants respectfully assert that the invention as presently claimed is not anticipated by Aleman. Hence, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) over Aleman are respectfully requested.

***IX. The First Rejection Under 35 U.S.C. § 103(a) Over Aleman and Wu Is Traversed***

In the Office Action at pages 5-6, the Examiner has rejected claims 1-5 and 33-34 under 35 U.S.C. § 103(a) as being obvious over Aleman in view of Wu *et al.*, *Proc. Natl. Acad. Sci. USA* 86:9412-9416 (1989) (of record in Applicants' Information Disclosure Statement filed January 25, 2001; hereinafter "Wu"). By the foregoing amendments, claims 33 and 34<sup>2</sup> have been cancelled without prejudice or disclaimer, thus rendering moot the portion of this rejection that may have applied to those claims. Applicants respectfully traverse this rejection as it may be applied to claims 1-5.

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d

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<sup>2</sup>Applicants again note that claim 34 has been indicated by the Examiner as potentially allowable. *See* Office Action at page 7. Thus, the present rejection of claim 34, although now moot, is believed to be in error.

1596,1598 (Fed. Cir. 1988). Specifically, there must be a reason, suggestion, or motivation in the cited art that would motivate one of ordinary skill to combine the references, and that would also suggest a reasonable likelihood of success in making or using the invention as claimed as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). In the present case, a *prima facie* case of obviousness has not been established.

Applicants reiterate and incorporate herein the remarks made above concerning the disclosure of Aleman. Aleman does not disclose, suggest, or otherwise contemplate the production of purified uricases containing no more than about 2% of aggregates larger than octamers. As noted above, the Examiner has effectively acknowledged this deficiency in Aleman by noting the allowability of an independent claim in the form of claim 1 as currently presented. Thus, Aleman is seriously deficient as a primary reference upon which to base a *prima facie* case of obviousness.

These deficiencies of Aleman are not cured by Wu. As the Examiner has acknowledged (*see* Paper No. 24 at page 8, second paragraph), Wu does not disclose the production of purified uricase that is substantially free of aggregates larger than octamers, let alone of a purified uricase containing no more than about 2% of aggregates larger than octamers. Hence, there would have been no motivation to combine the disclosures of Aleman and Wu in the attempt to make and use the presently claimed uricases.

Thus, neither Aleman nor Wu suggests that one of ordinary skill should combine the disclosures of these references in order to make and use the claimed invention, and one of ordinary skill would not otherwise have been motivated to combine their disclosures. Absent

such suggestion and motivation, the cited references may not be properly combined to render the claimed invention obvious. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). Accordingly, for reasons explained above and by the Examiner's own acknowledgment of allowability of claim 1 as currently presented, the burden required to sustain a *prima facie* case of obviousness has not been met. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) therefore are respectfully requested.

**X.     *The Second Rejection Under 35 U.S.C. § 103(a) Over Aleman and Wu Is Traversed***

In the Office Action at page 6, the Examiner has rejected claims 1-7, 9 and 33 under 35 U.S.C. § 103(a) as being obvious over Aleman in view of Wu. By the foregoing amendments, claim 33 has been cancelled without prejudice or disclaimer, thus rendering moot the portion of this rejection that may have applied to that claim. Applicants respectfully traverse this rejection as it may be applied to claims 1-7 and 9.

Applicants reiterate and incorporate herein the remarks made above concerning the disclosures of Aleman and Wu. These references do not disclose, suggest or otherwise contemplate the claimed invention, and one of ordinary skill would not otherwise have been motivated to combine their disclosures. In fact, as noted in detail above, the Examiner has already acknowledged the allowability of an independent claim in the form of claim 1 as currently presented. Accordingly, for reasons explained above and by the Examiner's own acknowledgment of allowability, the burden required to sustain a *prima facie* case of obviousness has not been met.

In view of the foregoing remarks, Applicants respectfully assert that claims 1-7 and 9 are not rendered obvious by Aleman and Wu, alone or in combination. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are therefore respectfully requested.

***XI. The Rejection Under 35 U.S.C. § 103(a) Over Aleman and Delgado Is Traversed***

In the Office Action at pages 6-7, the Examiner has rejected claims 1, 17-25 and 27-28 under 35 U.S.C. § 103(a) as being obvious over Aleman in view of Delgado *et al.*, U.S. Patent No. 5,880,255 (Doc. No. AB2, of record; hereinafter "Delgado"). Applicants respectfully traverse this rejection.

Applicants reiterate and incorporate herein the remarks made above concerning the disclosure of Aleman. Aleman does not disclose, suggest, or otherwise contemplate the production of purified uricases containing no more than about 2% of aggregates larger than octamers. As noted above, the Examiner has effectively acknowledged this deficiency in Aleman by noting the allowability of an independent claim in the form of claim 1 as currently presented. Thus, Aleman is seriously deficient as a primary reference upon which to base a *prima facie* case of obviousness.

These deficiencies of Aleman are not cured by the disclosure of Delgado, which does not disclose the production of purified uricases containing no more than about 2% of aggregates larger than octamers. Hence, there would have been no motivation to combine the disclosures of Aleman and Delgado in the attempt to make and use the claimed uricases.

Thus, Aleman and Delgado, alone or in combination, do not disclose, suggest or otherwise contemplate the claimed invention, and one of ordinary skill would not otherwise have been motivated to combine their disclosures. Moreover, any attempt to rely on allegedly inherent disclosure in Aleman to support a rejection under 35 U.S.C. §103 is legally impermissible. Accordingly, for reasons explained above and by the Examiner's own acknowledgment of allowability, the burden required to sustain a *prima facie* case of obviousness has not been met.

In view of the foregoing remarks, Applicants respectfully assert that claims 1, 17-25 and 27-28 are not rendered obvious by Aleman and Delgado, alone or in combination. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are therefore respectfully requested.

## ***XII. Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all of the outstanding objections and rejections, and allow all pending claims.

It is believed that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt consideration of the foregoing amendments and remarks, and allowance of all pending claims, are earnestly solicited.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Brian J. Del Buono  
Attorney for Applicants  
Registration No. 42,473

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1100 New York Avenue, N.W.  
Washington, D.C. 20005  
(202)371-2600

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